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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,066	12/03/2003	Athur C. Perry	1987.1-7 (040020)	7966

24243 7590 03/23/2007
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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/728,066	Applicant(s) PERRY ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1 and 20-22 in the reply filed on December 20, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 and 12-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perry (WO 94/14390 A1).

Referring to Figures 1, 3, and 4, Perry discloses an orbital implant comprising:

- (i) a substantially spheroid body *sized and shaped to be placed* (emphasis added to functional language) in the orbit;
- (ii) a coating ("coated" or "wrapped": see page 5, lines 23-29; page 13, line 34 to page 14, line 2) *sized and shaped to intimately contact* (emphasis added to functional language) a section of said body; and wherein said coating has a first portion having a first bioabsorbability and a second portion having a second bioabsorbability different from said first bioabsorbability. The orbital implant may be coated/impregnated with a first bioabsorbable portion/material (e.g., a vascularization agent) prior to (see page 16, lines 31-35; page 17, lines 4-6) or after (see page 17, lines 7-13) applying a second bioabsorbable portion/material (e.g., collagen, polyglycolic acid, or

Art Unit: 3738

polylactic acid coating/wrapping), which subject matter is not only well known in the art but is further disclosed at page 22, lines 4-14. The vascularization agent coating/wrapping will have a bioabsorbability rate/property. The biopolymer (e.g., collagen, polyglycolic acid, or polylactic acid) coating/wrapping will have a bioabsorbability rate/property different than the one from the vascularization agent coating/wrapping.

The bioabsorbable (see page 12, lines 5-26) coating/wrapping materials are disclosed as not causing undue adverse immune response (see page 11, lines 19-24). The coating/wrapping may further include therapeutic agents (see page 13, lines 7-8; page 14, lines 14-29), color-coding indicia (see page 22, lines 15-18), passageways *sized to allow* (emphasis added to functional language) fluid exchange therethrough (see page 16, lines 25-29; page 23, lines 34-37; page 28, lines 19-23), a surface having microtexturing (see page 14, lines 31-36; page 24, lines 14-15) and/or an outer surface which is smoother than a first surface (see page 12, lines 27-29; page 14, lines 31-36; page 24, lines 15-17), a thickness of less than one millimeter (see page 12, lines 27-29), and a thickness *selected to allow melting penetration* (emphasis added to functional language) using a handheld cautery (see page 29, lines 11-14).

The two coatings/wrappings are “separate” since they are not blended/mixed. Chemical and/or molecular bonds keep said first and second portions/materials bonded. Also, the two coatings/wrappings are “separate” since they are coated/wrapped at different time frames. Each of said coatings/wrappings will be covering (directly or indirectly) first and second outer surface sections of the porous core. The two coverings are still external to the core.

Art Unit: 3738

Response to Arguments

4. With regards to 102(b) rejection based on Perry (WO 94/14390 A1), Applicants' arguments filed December 20, 2006 have been fully considered but they are not persuasive. The Applicants argue that Perry does not disclose first and second "external" portions. The Examiner respectfully disagrees. The two coating "portions" (emphasis added) are still external to the core. As previously indicated, each of Perry's coatings/wrappings will be covering (directly or indirectly) first and second outer surface sections of the porous core (i.e., they are external to the core).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry (WO 94/14390 A1) in view of Ragheb et al. (WO 98/36784 A1).

Perry discloses the invention as claimed (see 102(b) rejection above) except for particularly disclosing the coating as comprising first and second "exposed" portions each having a different bioabsorbability rate from the other (notice that independent claim 29 claims those portions as "external", rather than "exposed", so the same reasoning applied against independent claim 1 also applies to independent claim 29). However, implants/prostheses comprising two or more external coatings are already known in the art. For example, Ragheb et al. disclose a

Art Unit: 3738

prosthesis (see Figure 6B; see page 27, lines 5-13) having a first coating of a first bioactive substance (layer 18) deposited/disposed along an outer first segment (one half of the prosthesis), and a second coating of a different second bioactive substance (layer 18') deposited/disposed along a second outer segment (the other half of the prosthesis). The first therapeutic drug/agent could be in the same or different class of therapeutic substance than the second therapeutic drug/agent (see pages 12-15; page 24, lines 3-5). Examples of therapeutic drugs/agents are disclosed at pages 12-15. The two coatings are external/exposed to the outer surface of the prosthesis in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed (see page 27, lines 5-13). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis having two coatings external/exposed to the outer surface of the prosthesis, as taught by Ragheb et al., with the prosthesis or Perry, in order to deliver two agents/drugs to the tissue to which the particular surface of the prosthesis is exposed.

Response to Arguments

7. With regards to the 103(a) rejection based on Perry (WO 94/14390 A1) in view of Ragheb et al. (WO 98/36784 A1), Applicants' arguments filed December 20, 2006 have been fully considered but they are not persuasive. The Applicants argue that: "*A person searching for ways of providing a plurality of bonding zones for a permanently implanted prosthesis would have no motivation to look into disclosures of drug delivery systems*". Also, the Applicants argue that: "*The Ragheb device is designed to deliver several agents at the same location, not at two or more locations*". The Examiner respectfully disagrees.

Art Unit: 3738

- a. The Ragheb et al. prosthesis/implant is intended to deliver one or more agents/drugs to the same or different locations. Also, the claim language does not require (i) the agent to be delivered to the same or different locations, and/or (ii) bonding zones.
- b. In response to Applicants' piecemeal analysis of the references, it has been held that one cannot show nonobviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981).
- c. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3738

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

March 12, 2007


David H. Wilco
Primary Examiner